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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/308,192	07/14/1999	ALAN GEORGE BAXTER	229752000600	5844

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EXAMINER
DEVI, SARVAMANGALA J N

ART UNIT	PAPER NUMBER
1645	25

DATE MAILED: 09/16/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.	Applicant(s)
09/308,192	Baxter
Examiner	**Art Unit**
S. Devi, Ph.D.	1645

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *three* MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1) ☒ Responsive to communication(s) filed on *Aug 25, 2003* .

2a) ☒ This action is **FINAL.** 2b) ☐ This action is non-final.

3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

4) ☒ Claim(s) *1, 8-19, and 22* is/are pending in the application.

4a) Of the above, claim(s) *11-19 and 22* is/are withdrawn from consideration.

5) ☐ Claim(s) _____ is/are allowed.

6) ☒ Claim(s) *1 and 8-10* is/are rejected.

7) ☐ Claim(s) _____ is/are objected to.

8) ☐ Claims _____ are subject to restriction and/or election requirement.

Application Papers

9) ☐ The specification is objected to by the Examiner.

10) ☐ The drawing(s) filed on _____ is/are a) ☐ accepted or b) ☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a) ☐ All b) ☐ Some* c) ☐ None of:

1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____ .
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

*See the attached detailed Office action for a list of the certified copies not received.

14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

a) ☐ The translation of the foreign language provisional application has been received.

15) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s). _____
4) ☐ Interview Summary (PTO-413) Paper No(s). _____
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other:

RESPONSE TO APPLICANT'S AMENDMENT

Applicant's Amendment

1) Acknowledgment is made of Applicant's amendment filed 08/25/03 (paper no. 24) in response to the non-final Office Action mailed 02/26/03 (paper no. 22).

Status of Claims

2) Claims 2-7 have been canceled via the amendment filed 08/25/03.

Claims 1, 8 and 9 have been amended via the amendment filed 08/25/03.

Claims 1, 8-19 and 22 are pending.

Claims 1 and 8-10 are under examination.

Prior Citation of Title 35 Sections

3) The text of those sections of Title 35 U.S. Code not included in this action can be found in a prior Office Action.

Prior Citation of References

4) The references cited or used as prior art in support of one or more rejections in the instant Office Action and not included on an attached form PTO-892 or form PTO-1449 have been previously cited and made of record.

Rejection(s) Moot

5) The rejection of claims 2-4 and 7 made in paragraph 7 of the Office Action mailed 02/26/03 (paper no. 22) under 35 U.S.C. 112, first paragraph, as are rejected under 35 U.S.C. § 112, first paragraph, as being non-enabling with regard to the scope, is moot in light of Applicant's cancellation of the claims.

6) The rejection of claim 7 made in paragraph 8(a) of the Office Action mailed 02/26/03 (paper no. 22) under 35 U.S.C. §112, second paragraph, as being indefinite, is moot in light of Applicant's cancellation of the claim.

7) The rejection of claims 2, 3 and 7 made in paragraph 10 of the Office Action mailed 02/26/03 (paper no. 22) under 35 U.S.C. § 102(b) as being anticipated by Stanford *et al.* (WO 85/05034), is moot in light of Applicant's cancellation of the claims.

8) The rejection of claims 2-4 made in paragraph 11 of the Office Action mailed 02/26/03 (paper no. 22) under 35 U.S.C. § 102(a) as being anticipated by Stosic-Grujicic *et al.*

(*Mikrobiologija* 33 (1): 27-36, 1996), is moot in light of Applicant's cancellation of the claims.

Rejection(s) Withdrawn

9) The rejection of claim 8 made in paragraph 8(b) of the Office Action mailed 02/26/03 (paper no. 22) under 35 U.S.C. §112, second paragraph, as being indefinite, is withdrawn in light of Applicant's amendment to the claim.

10) The rejection of claims 1 and 10 made in paragraph 10 of the Office Action mailed 02/26/03 (paper no. 22) under 35 U.S.C. § 102(b) as being anticipated by Stanford *et al.* (WO 85/05034), is withdrawn in light of Applicant's amendment to the claims and/or the base claim.

11) The rejection of claim 9 made in paragraph 8(a) of the Office Action mailed 02/26/03 (paper no. 22) under 35 U.S.C. §112, second paragraph, as being indefinite, is withdrawn.

Rejection(s) Maintained

12) The rejection of claims 1 and 8-10 made in paragraph 7 of the Office Action mailed 02/26/03 (paper no. 22) under 35 U.S.C. 112, first paragraph, as being non-enabling with regard to the scope, is maintained for part of the reasons set forth therein. Claim 1 still includes limitations, such as, 'component of MAPG or a chemical equivalent of MAPG'. The breadth of the claims encompasses the use of 'a component of MAPG' or 'a chemical equivalent of MAPG' from any species of *Mycobacterium* in the method of treatment of IDDM. A review of the instant specification shows that other than one MAPG, obtained from an undisclosed *Mycobacterium* species (Example 12 and Figure 6), no 'component of MAPG' or 'a chemical equivalent of MAPG' from any species of *Mycobacterium* has been enabled in a method of immunomodulatory treatment of IDDM. Example 4 describes that MAPG was obtained from the Tuberculosis Repository, but does not disclose which species of *Mycobacterium* was MAPG obtained from. Other than this MAPG, no other isolated mycobacterial cell components from any species of *Mycobacterium* have been used or administered to a mammal, human or non-human, in a method of immunomodulatory therapy for IDDM, wherein the administered component or equivalent has shown a significant therapeutic effect against IDDM, as currently claimed. As set forth previously, there is no showing that the components of MAPG, mycolic acid, arabinogalactan and peptidoglycan from one or more species of any *Mycobacterium*, were successfully used in a method of immunomodulatory treatment of IDDM. Without a concrete showing, there is no

predictability that MAPG from any species of *Mycobacterium*, any MAPG component ,or any chemical equivalent thereof, would indeed elicit immunotherapeutic effects against IDDM. The applied art (see below) establishes the unpredictability in the art by showing that every component or analog of a mycobacterial cell wall would not have a therapeutic effect against diabetes. For example, Stosic-Grujicic *et al.* showed that a mycobacterial cell wall analog (i.e., equivalent), MDP, did not produce any protective effect against IDDM. Clearly, the specification is not adequately enabling. The full scope of the claims is not commensurate with the enabling disclosure or evidence. Without isolation of MAPG, and isolation and identification f a component thereof or a chemical equivalent thereof from a representative number of specific species of *Mycobacterium* followed by their evaluation in human IDDM or non-human therapeutic models of IDDM, one of ordinary skill in the art would not be able to practice the full scope of the invention and therefore, would not be able to reproducibly practice the claimed invention without undue experimentation. Therefore, given the lack of specific disclosure and/or specific guidance in the specification, the breadth of the claims, quantity of experimentation required, and the associated unpredictability, one of ordinary skill in the art could not practice the full scope of the claimed invention, without considerable undue experimentation. The rejection stands.

13) The rejection of claim 1 made in paragraph 11 of the Office Action mailed 02/26/03 (paper no. 22) under 35 U.S.C. § 102(a) as being anticipated by Stosic-Grujicic *et al.* (*Mikrobiologija* 33 (1): 27-36, 1996), is maintained for reasons set forth therein and herebelow.

14) The rejection of claims 1 and 10 made in paragraph 12 of the Office Action mailed 02/26/03 (paper no. 22) under 35 U.S.C. § 103(a) as being unpatentable over Stosic-Grujicic *et al.* (*Mikrobiologija* 33 (1): 27-36, 1996), is maintained for reasons set forth therein and herebelow.

Applicant contends that Stosic-Grujicic *et al.* claim to prevent diabetes in a chemically induced model of diabetes. Applicant cites Hammond *et al. J. Exp. Med.* 187: 1047, 1998 and states that mice are considered diabetic when their blood glucose is >11.1 mMol. Applicant states that animals with streptozotocin and either TMD or PPD become diabetic within 14 days of treatment and therefore TMD or PPD fails to prevent diabetes. Applicant further submits that the amended claim 1 specifies that the cell wall components comprise MAPG, and that Stosic-Grujicic *et al.* discuss only treatments using TMD and PPD, but not MAPG.

Applicant's arguments have been carefully considered, but are non-persuasive. Stosic-Grujicic *et al.* taught the therapeutic effect of TDM, not TMD. Contrary to Applicant's assertion, the instantly claimed method is not a method of 'preventing' diabetes, but a method of treating of IDDM. Instant claims do not exclude chemically-induced IDDM. With regard to Applicant's remark on the blood glucose level of >11.1 mMol, it should be noted that the instant claims do not recite any specific marker for IDDM, or a particular level of glucose as an indicator of diabetes. Stosic-Grujicic *et al.* taught the recognition in the art of a protective role for *Mycobacteria* in IDDM. Stosic-Grujicic *et al.* demonstrated a positive effect of their 'derived' product(s) against diabetes. Stosic-Grujicic *et al.* taught that since CFA provided 'long-lasting protection from IDDM', they investigated the effects of 'various well-defined immunomodulatory (adjuvant and immunogenic) mycobacterial components' on diabetes. Stosic-Grujicic *et al.* further taught that two mycobacterial components 'derived' from mycobacterial 'cell wall', TDM and PPD, did protect mice from diabetes. See page 30. Since the length of therapeutic effect is not a required limitation or element of the instant claims, how long the product remains therapeutic is not relevant. Furthermore, since the exact structural composition of the 'chemical equivalent of MAPG' or 'component of MAPG' is not defined, Stosic-Grujicic's well-defined immunomodulatory mycobacterial components derived from the cell wall are viewed as being equivalent to, or as containing a 'chemical equivalent of MAPG' or a 'component of MAPG', and therefore are able to bring about the same therapeutic effect against diabetes as that of the Applicant's product. The rejection stands.

New Rejection(s)

Applicant is asked to note the following new rejection(s) made in this Office. The new rejections are necessitated by Applicant's amendments to the claims and/or the base claims.

Rejection(s) under 35 U.S.C. § 112, Second Paragraph

15) Claims 1 and 8-10 are rejected under 35 U.S.C. § 112, second paragraph as being indefinite for failing to particularly point out and distinctly claim the subject matter which Applicant(s) regards as the invention.

(a) Claim 1 is vague and confusing in the use of an abbreviation in the claim language: "IDDM". It is suggested that the abbreviation be recited as a full terminology at first occurrence,

with its abbreviated recitation retained in parentheses.

(b) Claims 1 and 9 are vague and confusing in the recitation: "a component of MAPG" or "a chemical equivalent of MAPG". It is unclear what is encompassed in these limitations. Since the MAPG recited in the claims encompasses or includes an unpurified MAPG, what qualifies as a "a component of MAPG" or "a chemical equivalent of MAPG" is not clear. Is an impure or contaminant component associated with MAPG encompassed in the scope of the limitations. What constitutes a 'component of MAPG', or 'a chemical equivalent of MAPG', and how much of the MAPG's original structure has to be retained such that the resulting product can be considered as a 'component of MAPG', or 'a chemical equivalent of MAPG', is not clear. The metes and bounds of the structure encompassed in the limitations 'component of MAPG', or 'a chemical equivalent of MAPG' is indeterminate.

(c) Claim 1 is confusing, redundant and/or incorrect in the recitation 'a component of MAPG, ...a component of MAPG' (see lines 4 and 5).

(d) Claims 8-10, which depend directly or indirectly from claim 1, are also rejected under 35 U.S.C. § 112, second paragraph, as being indefinite, because of the indefiniteness or vagueness identified above in the base claim(s).

Remarks

16) Claims 1 and 8-10 stand rejected.

17) Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See M.P.E.P § 706.07(a). Applicants are reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 C.F.R 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

18) Papers related to this application may be submitted to Group 1600, AU 1645 by facsimile

transmission. Papers should be transmitted via the PTO Fax Center located in Crystal Mall 1. The transmission of such papers by facsimile must conform with the notice published in the Official Gazette, 1096 OG 30, November 15, 1989. The CM1 facsimile center's telephone number is (703) 308-4242, which is able to receive transmissions 24 hours a day and 7 days a week. The RightFax number for submission of before-final amendments is (703) 872-9306. The RightFax number for submission of after-final amendments is (703) 872-9307.

19) Any inquiry concerning this communication or earlier communications from the Examiner should be directed to S. Devi, Ph.D., whose telephone number is (703) 308-9347. The Examiner can normally be reached on Monday to Friday from 7.45 a.m. to 4.15 p.m. except one day each bi-week, which would be disclosed on the Examiner's voice mail system. A message may be left on the Examiner's voice mail system.

If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's supervisor, Lynette Smith, can be reached on (703) 308-3909.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0196.

September, 2003

S. DEVI, PH.D.
PRIMARY EXAMINER